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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* NO. 9 TO EXCLUDE EVIDENCE OF TRADE ASSOCIATIONS, SOCIETIES, OR ORGANIZATIONS

(Assigned to the Honorable David G. Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") submit this response in opposition to Plaintiff's Motion *in Limine* No. 9 and respectfully show the Court as follows:

ARGUMENT AND CITATION OF AUTHORITY

A. Such Material Is Admissible as Non-Hearsay, an Exception to Hearsay, and as a Basis of Opinions Offered by Bard's Medical Experts.

The Plaintiff argues that "medical societies' statements constitute inadmissible hearsay . . . to the extent that they are offered for the truth of the matter asserted." (Pl.'s Mot. at 2.) Bard need not be offering such statements for the truth of the matter asserted, however. Therefore, the Plaintiff's argument fails.

Under Georgia's risk-utility test for design defect, juries may consider, among other factors, the likelihood of the danger, the user's knowledge of the product, publicity surrounding the danger, common knowledge, the state of the art at the time the product is manufactured, and proof of compliance with industry-wide practices. *See Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 675 n.6 (Ga. 1994). Statements of medical societies, about IVC filters and reported complications with IVC filters, regardless of truth of those statements, are relevant to the jury's consideration of these risk-utility factors. For example, the *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism*, published periodically since 2001 by the Society of Interventional Radiology ("SIR") addresses reported rates of IVC filter complications generally seen by physicians as reported in the medical literature. The SIR Guidelines discuss the complications of fracture, tilt, migration, and penetration of the IVC, citing to articles in the medical literature. The jury should be able to consider this evidence when weighing whether these complications amounted to "common knowledge," and when assessing "publicity surrounding the danger" of these complications, for instance.

Likewise, such statements that were provided to the medical community (whether true or not), are relevant to the jury's consideration of whether Bard's warnings were

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adequate and whether any such failure caused her physician to use the G2® Filter instead of a different filter. *See, e.g., Thornton v. E.I. Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994) (discussing duty to warn under Georgia law of "nonobvious" foreseeable dangers and the need to provide "an adequate warning").

Even if statements by medical societies are offered for the truth of the matter asserted, they reflect statements in learned treatises, periodicals, or pamphlets under Federal Rule of Evidence 803(18), and therefore are admissible as an exception to the hearsay rule. And regardless of hearsay, Bard's medical experts have relied on, and properly disclosed their reliance on, the SIR Guidelines in forming their opinions, and therefore Bard's experts' opinions based on the SIR Guidelines are admissible under Rule 703, and were unchallenged by the Plaintiff in any *Daubert* motions.

Finally, counsel for the Plaintiff may cross examine witnesses who address the SIR Guidelines and any other associations, trade groups, organizations, or societies of physicians; Plaintiff may also call her own witnesses, and argue to the jury about the relative significance of such statements and non-statements.[1]

Accordingly, what medical societies, like the SIR, say or do not say about risks of IVC filters generally and/or of Bard's G2® Filter specifically are relevant to the jury's consideration of the Plaintiff's design and warning claims and should be admissible on numerous grounds.

B. *Daubert* and Rule 703 Are Inapplicable.

The Plaintiff's argument that Bard will attempt to offer expert opinions through fact witnesses is inaccurate. The SIR Guidelines, however, were discussed routinely among Bard employees and with the FDA. These fact witnesses should be permitted to testify and be cross examined about things they said and actions they took during the

[1] Plaintiff incorrectly argues that absence of a statement from medical societies constitutes hearsay. *See e.g., Llamas v. Seibel*, No. 16-CV-05812-WHO, 2017 WL 3782175, at *8 (N.D. Cal. Aug. 31, 2017) ("Testimony regarding the *absence* of a statement is not hearsay.") (emphasis original); *see also, e.g.*, Fed. R. Evid. 801 ("'Statement' means a person's oral assertion, written assertion, or nonverbal conduct, if the person intended it as an assertion.").

course of their employment concerning the SIR Guidelines. Moreover, the Plaintiff has developed extensive expert opinion to rebut any testimony that counsel purports to be concerned about. (*See e.g.*, Expert Report of Drs. Kinney, Roberts, and Kalva, Doc. 7300 Exhibit G, at pp. 86-104.) As such, *Daubert* and Rule 703 are inapplicable.

C. Any Danger of Prejudice or Waste of Time Is Not Substantially Outweighed by the Probative Value.

The foundation for the Plaintiff's argument is that, in other cases, Bard used the SIR Guidelines to establish acceptable safety thresholds and complication rates. But the Plaintiff's claim is inaccurate, and the Plaintiff has cited nothing to the contrary. The Plaintiff also claims that the SIR Guidelines are irrelevant because they concern only permanent filters. But the G2® Filter at issue in Ms. Booker's case was first cleared as a permanent filter before receiving clearance as a retrievable filter. And although the 2001 and 2003 SIR Guidelines concern permanent filters, the 2011, 2016, and 2017 SIR Guidelines concern both permanent and retrievable filters. Finally, the Plaintiff argues that the SIR Guidelines will result in "mini-trials," but efficient management of the evidence and adherence to the Court's time limits will avoid this issue. As discussed above, the SIR Guidelines are relevant to the jury's consideration of Georgia's risk-utility test and the Plaintiff's failure-to-warn claim, and they are factually relevant to what Bard did and said regarding its G2® Filter. Indeed, excluding the SIR Guidelines would risk confusing the jury because many relevant events in this case refer to or relate to the SIR Guidelines, and discussion of the SIR Guidelines therefore will provide the jury with necessary context. In short, the Plaintiffs have not demonstrated at this *in limine* stage that the probative value of the SIR Guidelines, and any other evidence of trade associations, societies, or organizations, is "substantially outweighed" by the danger of unfair prejudice and "unnecessary mini trials."

CONCLUSION

For these reasons, Bard respectfully requests that this Court deny the Plaintiff's Motion *in Limine* No. 9.

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RESPECTFULLY SUBMITTED this 9th day of February, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of February, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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